

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
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Title: <b>Informed Consent process</b>	Date Effective 9-16-04	Supercedes P&P dated

## Persons Unable to Give Consent

### Proxy Consent

Federal regulations stipulate that no investigator may involve a human being as a subject in research unless the investigator has obtained legally effective informed consent from the subject or the subject's LAR. For research conducted in Maryland, the following classes of persons, in order of priority, are authorized under the Maryland Health Care Decisions Act of 1993 to provide consent for health care on behalf of a subject who is unable to consent for him or herself and who has not appointed a health care agent:

- Guardian
- Spouse
- Adult Child
- Parent
- Adult Sibling
- Friend or other relative, provided that person is competent and presents an affidavit to the investigator stating that:
  - the person is a close friend or relative, and
  - the person has maintained regular contact with the subject.

For additional information concerning proxy consent, please contact the Office for Research Subjects. See also [Decisionally Impaired Subjects](#).

### Parental Permission/Child Assent

Written permission from parents is usually required for research involving minor children. Children 7 through 17 years of age should also be given the opportunity to agree, or not agree, to participate in research. Children in this age group usually provide consent by signing a written "assent form" that is tailored to age-specific groups. Some children less than age 7 are capable of providing assent and investigators should be sensitive to these groups by tailoring the consent process based on the population. See [Sample Child Assent](#).

Parental permission is also required for research that involves children. The signature of one parent or legal guardian is usually sufficient for research that is not greater than minimal risk or is greater than minimal risk but has the prospect of direct benefit to the child. The requirement for parental consent may vary depending upon the state in which the research will be carried out. Investigators should be familiar with state and local laws concerning parental permission for research involving children. For example, in Maryland, parental permission is not required

for research involving treatment of minors with STDs. Also see [CHR Policy on Research Involving Children](#) and [CHR Form M: Research Involving Children Checklist](#).

Persons who are cognitively impaired

See [Decisionally Impaired Subjects](#)